Applicant: Brian Cox et al. PATENT Serial No.: 10/774,299 Atty Docket: 388700-612-05-CIP2

Art Unit: 4133

REMARKS

This Amendment is filed in response to the Office Action mailed June 11, 2008. In this Amendment, claims 20, 22 and 23 are amended and claims 1-19, 21 and 24 are unchanged. Following entry of this amendment, claims 1-24 shall be pending, with claims 1-12 having been previously withdrawn.

In the Office Action, claim 22 is rejected because of insufficient antecedent basis. and claims 13-24 have been rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

REJECTIONS UNDER 35 USC § 112

The Examiner notes that Claim 22, which depends from Claim 13, recites the limitation "the step of generating an electrical signal," which appears in Claim 14, not Claim 13. Accordingly, Claim 22 has been amended to depend from Claim 14. Furthermore, Applicant notes that Claim 23 also recites this limitation and depends from Claim 13. Accordingly, Claim 23 has also been amended to depend from Claim 14. The Applicant believes that all of the § 112 issues have been resolved by these amendments and requests that these rejections be withdrawn.

Additionally, the Applicant notes that Claim 20 was missing an antecedent "the" before "coupling element" and amended Claim 20 accordingly. Also, a colon ":" was missing after "the steps of" in the preamble of Claim 22. No new matter has been added by way of these amendments.

II. REJECTIONS UNDER 35 USC § 103

The Examiner rejected Claims 13, and 15-21 under § 103 as being unpatentable over Goodson et al. (US 6,117,142, hereinafter "Goodson") in view of Lulo (US 6,544,225, hereinafter "Lulo").

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With regard to Claim 13, he Examiner states that Goodson discloses steps (a). (d), and (e), while Lulo discloses steps (b) and (c). The Applicant respectfully disagrees.

For example, neither Goodson nor Lulo teaches or suggests a purge passage being formed through a coupling element. While Lulo teaches an aperture 130 for removal of air from a deployment device, the aperture 130 is only taught as being disposed on the wall of the distal end of a deployment catheter, not as part of a coupling element attached to the endovascular device as claimed. The placement of this passage constitutes a patentable distinction for multiple reasons.

For example, in the design shown in Lulo, there exists a risk that an embolic coil may be inserted too far into the deployment catheter, thereby blocking the aperture 130 and preventing air from being purged from the deployment system. In contrast, placement of the purge passage through the coupling element completely avoids this risk.

If the Lulo aperture is moved proximally to reduce this risk, room is left for an air bubble to remain distal of the aperture. Lulo even warns of this possibility at column 4, lines 33-36. If the aperture is too far from the seal plug 122, air will remain in the lumen. If the aperture is blocked by the seal plug 122, air will not be purged. Hence, Lulo presents a design with an unnecessarily tight design tolerance, when compared to the designs of the present invention.

Claims 15-21 depend, directly or indirectly, from Claim 13 and are therefore also patentable. Additionally, there exist independent reasons for patentability of these claims.

For example, Claim 18 recites that the retention sleeve is not substantially expanded in the radial direction during the injection step. The Examiner has rejected Claim 18, stating that Goodson shows a retention sleeve that is not substantially expanded at Figures 3 and 8 (item 116), and column 4, lines 32-52. This is simply not true. Item 116 is described as being located proximal of the retention sleeve (which is

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item 108). Item 108, the distal retention sleeve that retains the implant, is specifically described as having a lower durometer than the proximal portion so that it may expand radially to release the implant. The reason the proximal portion is designed not to expand is because it needs to be able to transfer the fluid pressure to the retention sleeve 108. If it expanded, the fluid pressure would be reduced and there would be the risk that the retention sleeve 108 would not expand and release the implant.

The present invention, in stark contradistinction, uses the fluid pressure to eject the implant from the retention sleeve, rather than to expand the retention sleeve away from the implant. Hence, the retention sleeve of the present invention does not substantially expand in the radial direction during the injection step.

Claim 20 recites the method of Claim 13, wherein the coupling element has an exterior surface, and wherein the purge passage is formed in the exterior surface of the coupling element. The Examiner states that Lulo shows such a coupling element. Lulo does not. The coupling element, as claimed, is attached to the proximal end of the filamentous device and is releasably attached to the deployment tube. The purge passage of Lulo is formed in the deployment tube, not in the coupling element.

Claim 21 recites that the purge passage is helical. The Examiner admits that Lulo does not disclose a helical purge passage but asserts that it would have been obvious to one skilled in the art to modify the Goodson device to include a helical purge passage as shown by Lulo (even though the Lulo passage is not helical). The Examiner makes a conclusory statement that the shape of the purge passage would be adjusted to the particular location in the vasculature to meet the needs and goals of the Goodson procedure. The Applicant disagrees. The Goodson and Lulo devices are nearly identical, with the exception of the purge passage. The Lulo purge passage is formed in the deployment tube, not the coupling element. If one skilled in the art were to modify the Goodson device and received inspiration for doing so from Lulo, one skilled in the art would simply form the passage through the deployment tube that Lulo teaches. The
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Examiner gives no further explanation how one skilled in the art would be inspired to modify the *Goodson* implant to include a helical purge passage after reading *Lulo*.

Hence, Claims 13 and 15-21 are patentable over *Goodson* in view of *Lulo*. The Applicant has effectively traversed these rejections and respectfully requests the withdrawal of these rejections and an indication of allowance of these claims.

Claim 14 and 22-24 are rejected under 35 USC § 103(a) as being unpatentable over Goodson in view of Lulo further in view of Pahno et al. (US 5,269,030, "Pahno"). With regards to Claim 14, Claim 14 depends from Claim 13 and is therefore patentable as being dependent from a patentable base claim. Additionally, however, Claim 14 is independently patentable. Claim 14 recites generating an electrical signal in response to the separation of the endovascular device from the deployment tube. The Examiner points to Pahno, column 34, lines 39-61 for this disclosure. The Applicant strongly disagrees and would like to point out that Pahno relates to a hospital bed that includes a complicated bedpan system for receiving and disposing of patient waste without requiring the patient to move. The cited passage discusses a warning signal generated in the event that a water rinse jug becomes disconnected. This is completely nonanalogous to the present invention. Rather than finding a reference that teaches the generation of an electrical signal in response to the separation of the endovascular device from the deployment tube, or even the generation of an electrical signal in response to the separation of any medical implant from any delivery device, the Examiner had to resort to a reference that shows the generation of an electrical signal in response to the separation of a water jug from a bedpan system. That the Examiner failed to find more analogous art to the claimed invention is itself evidence of the nonobyjousness of Claim 14.

The Supreme Court's decision in KSR International Co. v. Teleflex Inc. (KSR), 550 U.S. ____, 82 USPQ2d 1385 (2007) loosened the rigidity of the application of the factors set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966)), but did reaffirm the framework of using these factors to determine obviousness. Hence, the

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three factors arising from *Graham* still apply, namely: (1) the scope and contents of the prior art; (2) the differences between the prior art and the claims in issue; and (3) the level of ordinary skill in the pertinent art.

Even with the less rigid application of these factors under KSR, Pahno falls well short of rendering Claim 14 obvious. For example, as to factor (1), Pahno does not disclose an endovascular device or a deployment tube. As to factor (2), the differences between Pahno and Claim 14 are vast. Pahno, as stated above, relates to a large, complicated, hospital bed while Claim 14 relates to a method of deploying an endovascular device. Hence, Claim 14 is not obvious over Goodson and Lulo in view of Pahno.

Claim 22-24 depend directly or indirectly from Claim 14 and are patentable thereby. Claims 22-24 also depend indirectly from Claim 13 and derive further patentability therefrom. Additionally, the Examiner again relies on *Pahno* to reject Claims 22-24. Applying *Pahno* against Claims 22-24 is inappropriate for the reasons described with regards to Claim 14.

Hence, Claims 14 and 22-24 are patentable over *Goodson* in view of *Lulo* in further view of *Pahno*. The Applicant has effectively traversed these rejections and respectfully requests the withdrawal of these rejections and an indication of allowance of these claims.

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CONCLUSION

In view of the foregoing, it is submitted that pending claims 13-24 are now in condition for allowance. Hence, an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,

Dated: October 14, 2008

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